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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/003,621 11/02/2001 Artur Mitterer 20695D-000110US 6242

20350 7590 06/02/2004

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
	1653

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,621	MITTERER ET AL.	
	Examiner Hope A. Robinson	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 17-19, 24-26 is/are rejected.
- 7) Claim(s) 20-23,27 and 28 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed December 15, 2003 on March 15, 2004 is acknowledged.
2. Claims 1-16 have been canceled. Claims 23-28 have been added. Claims 17-20 have been amended. Claims 17-28 are pending and are under examination.
3. The following grounds of rejection are applicable:

Claim Objection

4. Claim 18 is objected to for the recitation of "factor VIII/vWF-complex" instead of "factor VIII/vWF-complex".
Correction is required.

Priority

5. It is noted that applicant filed foreign priority documents on May 17, 2004 which have been entered. The document is in German. To perfect priority, an appropriate certified translation into English is necessary.

Specification

6. The specification is objected to because of the following informalities:
the specification is objected to because on page 3, lines 3-4, the following appears "The elution of the FVIII/vWF-complex adsorbed on the cation exchanger there is effected by using a Ca-containing buffer....", note that the sentence is unclear. See also page 6 line 16, where the following appears "... the size of vWF ranging from 500 000 to several millions...".
7. The Drawings filed on March 15,2004 have been received and entered.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Amended claim 18 is indefinite for the recitation of "free from inactive vWF degradation products" as it is unclear if this means the product contains active vWF degradation products or has no vWF degradation products, and the instant specification

does not provide any detail regarding what is intended with this language. It is suggested that applicant delete the term "inactive".

Basis For NonStatutory Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 17-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,228,613. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a factor VII/vWF-complex that comprises high molecular weight vWF multimers and free from low molecular weight vWF and vWF degradation products and the instant claims are directed to a factor VIII/von WF-complex containing high-molecular weight vWF and free from low-molecular weight vWF multimers. With secondary claims in the instant application to a factor VIII/vWF-complex free from vWF degradation products and having specific activity which falls within the range of patented claim 23. Therefore, the claims in the patent makes obvious the claimed invention in the instant application as it encompasses the claimed invention in the instant application. Although the scope of the claims herein differs, the two sets of claims are directed to similar subject matter. Thus, the instant application claim is an obvious variation of the copending application claim.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

12. Claims 24-26 are rejected under 35 U.S.C. 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arrighi et al. (EP 600480, December 4, 1993).

Arrighi et al. disclose a factor VIII-von Willebrand Factor complex extracted from total plasma comprising purification via a cationic exchanger (claims 24-26). This rejection has been made as a 102/103 rejection in view of the product-by-process format of the claims. Although Arrighi et al. do not the process recited in the claims, however, the product is taught. Claims 24-26 are product by process claims and if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the claimed product was made by a different process. The patentability of a product does not depend on its method of production (see MPEP 2113). While the reference does not specifically teach all the steps of the process (see claims 25-26), the production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner (see *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972).

13. Claims 24-26 are rejected under 35 U.S.C. 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burnouf et al. (*Protein Expression and Purification*, vol. 5, pages 138-143, 1994).

Burnouf et al. disclose a purified factor VIII-von Willebrand Factor-complex from human plasma (claims 24-26). This rejection has been made as a 102/103 rejection in view of the product-by-process format of the claims. Although Burnouf et al. do not

disclose the process recited in the claims, the product is taught. Claims 24-26 are product by process claims and if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the claimed product was made by a different process. The patentability of a product does not depend on its method of production (see MPEP 2113). While the reference does not specifically teach all the steps of the process (see claims 25-26), the production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner (see *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); *In re Brown*, 173 USPQ 685 (CCPA 1972).

14. Claim 17 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (EP 705,846, October 4, 1996).

Fischer et al. teach the binding of factor VIII with vWF (thus a factor VIII/vWF-complex, see figure 4, the abstract and page 15 of the reference) and the instant specification discloses on page 3 that the reference teaches the separation between high and low molecular fractions of recombinant vWF, which serves as admitted prior art. Therefore, it would have been obvious to arrive at the claimed invention as a whole as Fischer et al. teach a factor VIII/vWF complex and the separation of low and high molecular weight vWF multimers and it is well known in the art that the high molecular weight vWF is preferred based on its association with bleeding time. (see page 3 of the

instant specification). Thus, the claimed invention was obvious to make and use and is prima facie obvious.

15. Applicant's response filed March 15, 2004 has been considered. Note that new grounds of rejections have been instituted based on the amendments to the claims, for example, the rejections under 35 U.S.C. 112, second paragraph, 103(a), obvious type double patenting and 102/103, the art rejections over the product-by-process claims newly submitted. With regard to the reference cited by Arrighi et al. page 10 of the response distinguishes the process used by the reference and the claimed process. However, the reference and the claimed invention teach the factor VIII/vWF-complex and as such the process of obtaining the product is not relevant, unless the properties of the product are changed by the process of making said product. Therefore, the Arrighi et al. reference remains relevant and is applied to the newly submitted claims. The Burnouf et al. reference cited is applied to the claims for the same reasons as set forth above. Note that claim 17 remains rejected under 35 U.S.C. 103(s), however, the rejection has been amended to fit the amendments made to the claim. On page 13 of the response it is stated that the Fischer et al. reference focuses on methods for purifying vWF rather than factor VIII/vWF complexes, however, this statement is not accurate based on the disclosure on page 15 of the reference. Thus, the Fischer et al. reference remains for the reasons stated above.

Conclusion

16. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-

0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

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